Methods: We retrospectively analyzed data from patients with massive and submassive PE treated with USAT over a 2-year period. EKOS catheters (EkoSonic Endovascular system, EKOS Corp., Bothell, WA) were placed in the largest lower lobe pulmonary artery, bilaterally in 14 patients (93%) and unilaterally in 1 patient (7%). Recombinant t-PA was administered through the EKOS catheters as a 5 mg bolus followed by 1 mg/hour for a maximum dose of 20 mg.
Results: Fifteen patients received USAT for PE between May, 2010 and April, 2012. Ten patients (67%) presented with saddle emboli. Four patients (27%) presented with massive PE requiring inotropic support and mechanical ventilation. Technical success in EKOS catheter placement was 100%. Pre-USAT echocardiographic RV/LV diameter ratios were obtained in 13 (87%) patients and were abnormal in 12 (92%) patients (mean 1.23 ± 0.28). After USAT, 5(33%) patients had follow-up echocardiograms, in which the RV/LV ratio normalized in all patients (mean 0.83 ± 0.06) (p=0.07). Mean pulmonary artery (PA) pressures were 39.9 ± 2.1 before treatment and 31.2 ± 3.2 after treatment (p = 0.03). Three patients (20%) had follow-up angiography, of which 2 (67%) had complete resolution of emboli. Mean hospital stay was 10.8±8.59 days. Thirteen patients (87%) were discharged alive. One patient (7%) required a blood transfusion.
Conclusions: In patients with massive and submassive PE, USAT restores hemodynamic stability and reverses right ventricular dilatation and with minimal risk of bleeding complications.

Structural, Non-Valvular Intervention

Hall D

Tuesday, October 23, 2012, 8:00 AM–10:00 AM

Abstract nos: 760-769

POSTERS

TCT-760

Mid-term Outcomes of Alcohol Septal Ablation for Obstructive Hypertrophic Cardiomyopathy in Patients with Sigmoid versus Neutral Ventricular Septum

Josef Veselka[1], Pavol Tomasov[1], David Zemanek[1]
[1]2nd Medical School, Charles University, University Hospital Motol, Prague 5, Czech Republic

Background: The aim of this study was to determine whether the differences in the baseline septal morphology influenced outcomes of patients after alcohol septal ablation (ASA).
Methods: A total of 100 consecutive, highly symptomatic patients with HOCM and a neutral or sigmoid septum (74 patients vs 26 patients) underwent ASA and were examined clinically and echocardiographically at baseline and at follow-up (median 30 months vs 24 months).
Results: At baseline, a neutral septum morphology was associated with a thicker basal septum [21 (19-24) mm vs 19 (18-20) mm; p<0.01] and higher pressure gradient at rest [59 (39-80) mm vs 43 (33-50) mm; p<0.01], but a similar pressure gradient after provocation [100 (72-120) mmHg vs 97 (70-110) mmHg; p=0.31], and subsequently both resting gradient [10 (10-16) mmHg vs 12 (10-15) mmHg; p=0.67] and provoked gradient after ASA [20 (10-30) mmHg vs 18 (12-25) mmHg; p=0.71]. Four patients died during follow-up (4% vs 1%; NS). Pressure gradient, septum thickness and symptoms decreased significantly in both groups.
Conclusions: Patients treated with ASA who had a sigmoid septum were characterized at baseline by a thinner basal septum and lower pressure gradient at rest. However, they showed an identical pressure gradient after provocation and subsequently after ASA. ASA was safe and effective in both groups of patients.

TCT-761

Complications of Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy with Focus on Complete Heart Block: A European Multicenter Study

Josef Veselka[1], Thorsten Lawrenz[2], Christoph Stellbrink[3], David Zemanek[1], Marian Branny[4], Jaroslav Januska[4], Ladislav Groch[5], Pawel Dimitrow[6], Jan Krejci[7], Maciej Dabrowski[8], Stanislav Mizera[9], Horst Kuhn[3]
[1]2nd Medical School, Charles University, University Hospital Motol, Prague 5, Czech Republic, [2]Klinikum Bielefeld-Mitte, Department of Cardiology and Internal Intensive Care, Bielefeld, Bielefeld, Germany, [3]Klinikum Bielefeld-Mitte, Department of Cardiology and Internal Intensive Care, Bielefeld, Germany, [4]Department of Cardiology, Podlesi Hospital, Trinec, Trinec, Czech Republic, [5]Department of Cardiology, Pleven, Pleven, Bulgaria, [6]2nd Department of Cardiology, Collegium Medicum, Jagiellonian University, Cracow, Poland, [7]1st Department of Internal Medicine/Cardioangiology, International Clinical Research Center –St. An, Brno, Czech Republic, [8]Department of Interventional Cardiology and Angiology, Institute of Cardiology, Warsaw, Poland, [9]Department of Cardiology, National Institute of Cardiovascular Diseases, Bratislava, Slovakia

Background: Alcohol septal ablation (ASA) is a catheter-based intervention that has been used as an alternative to surgical myectomy in highly symptomatic patients with hypertrophic obstructive cardiomyopathy (HOCM). However, clinically relevant complications can result, including death and complete heart block (CHB) associated with syncope or resuscitation.This study was designed to evaluate the incidence of major complications with a focus on CHB after ASA for HOCM.
Methods: This international, multicenter, retrospective study reviewed 545 patients who were treated using ASA; 421 (77%) met the inclusion criteria for this study. Clinical and echocardiographic follow-up (3–6 months) was completed in 394 patients (94%).
Results: ASA led to a significant reduction in symptoms and outflow gradient. One patient (0.2%) died of cardiac tamponade four days after ASA. Two other patients (0.5%) died several weeks after ASA (sudden death of unknown cause). Sustained ventricular arrhythmias occurred within hospital stay in three patients (0.7%). A total of 70 patients (17%) developed mostly transient intra/post-procedural CHB; in 30% of them, CHB occurred/reoccurred later than 24 hours after ASA. Ninety-seven percent of CHB occurred until the fifth post-ASA day. Permanent pacemakers for CHB were implanted in 35 patients (8%). Multivariate analysis identified the intra-procedural bundle branch block and age as independent predictors of CHB.
Conclusions: In this multicenter study, ASA was clinically effective in highly symptomatic patients undergoing a first intervention for HOCM. The most frequent major post-procedural complication was CHB (17%) that occurred late or recurred in almost one-third of these cases (5%). Ninety-seven percent of all CHB cases occurred until the fifth post-procedural day. Independent predictors of its development were intra-procedural bundle branch block and age of patients. Difficulties in predicting CHB should lead to close post-procedural monitoring and hospital stays lasting at least 5 days. Generally, these results highlight the importance of proper interventional training and establishing complex "HCM centers" as a prerequisite for all institutions offering ASA.

TCT-762

Abstract Withdrawn

TCT-763

Impact of left atrial appendage occlusion, with percutaneous device on left atrial function

Pedro Almeida[1], Eduardo Infante de Oliveira[1], João Marques[1], Fernando Ribeiro[1], Pedro Canas Silva[1], António Nunes Diogo[1], Fausto Pinto[1]
[1]Hospital de Santa Maria - CHLN, Lisboa, Lisboa

Background: Favorable results with the occlusion of the left atrial appendage (LAA), using percutaneous devices, for thromboembolic events prevention, has lead to a widespread use of this technique. However, the long-term effects on left atrial (LA) function are unclear. The objective of this study was to evaluate the impact of LAA occlusion on LA function.
Methods: LAA occlusion by percutaneous femoral access was performed in five female common swine, in sinus rhythm. TEE evaluation of LA dimensions using 2D, mitral and pulmonary veins (PV) Doppler flow, and TDI of mitral annular motion was performed at baseline and after 90 days.
Results: Four animals survived until the 90 days. Weight and body surface area increased from 53.0±4.7Kg/1.3±0.1m2 to 74.1±1.5Kg/1.6±0.4m2. At basaline, minimum LA diameter, area and volume were 22.0±2.1 mm/m2; 5.6±0.4cm2/m2 and 12.1±1.1cm3/m2. Maximum LA diameter, area and volume were 27.6±3.7mm/m2;7.8±1.0cm2/m2 and 19.1±4.0cm3/m2. At 90 days, systolic diameter, area and volume were 19.5±2.9mm/m2; 5.5±0.6cm2/m2 and 13.2±1.4cm3/m2 and diastolic values were 40.1±5.6mm/m2; 8.9±1.5cm2/m2 and 27.1±6.0cm3/m2. LA ejection fraction significantly increased from 35±9% to 50±7% at 90 days (p=0.038). There was a significant increase in LA maximal diameter (p=0.04) and a trend toward LA maximal volume increase from baseline to follow-up (p=0.082). There was a significant increase of E wave VTI (p=0.024) from 7.4±0.6cm to 10.5±1.4cm. TDI of mitral annulus showed E', A' and S' basal velocities of 10.8±2.7cm/s; 8.4±2.4cm/s and 8.4±1.6cm/s with no significant changes to follow-up. The E/E' ratio suffered no significant change, and there was a trend towards peak A' wave velocity (p=0.067). Baseline PV flow velocities were: S 65.0±2.8cm/s; A 31.0±8.5cm/s and D 51.0±7.1cm/s. At 90 days, S, A and D, were 55.0±4.2cm/s; 21.5±3.5cm/s and 44.5±6.4cm/s. The S/D ratio was 1.3±0.1 at baseline and 1.3±0.3 at 90 days. The D velocity at follow-up, revealed a significant reduction relative to the baseline (p=0.049).
Conclusions: This study provides initial evidence that LAA occlusion may not significantly impair LA function and does not lead to armful atrial remodeling or loss of contractile function.

TCT-764

Safety and Biocompatibility of the Coherex WaveCrest™ Left Atrial Appendage Occluder in a 30-Day Canine Study

Yanping Cheng[1], Jenn McGregor[1], Robert Sommer[2], William Gray[2], Daryl Edmiston[3], Gerard Conditt[1], Genghua Yi[1], Armando Tellez[1], Serge Rousselle[4], Juan Granada[1], Greg Kaluza[1]
[1]Cardiovascular Research Foundation, Orangeburg, NY, [2]Columbia University Medical Center, New York, USA, [3]Coherex Medical, Salt Lake City, UT, [4]Alizée Pathology, LLC, Thurmont, MD

Background: Left atrial appendage (LAA) occlusion is proposed to reduce the risk of thromboembolic stroke in atrial fibrillation patients.
Methods: WaveCrest™ (Coherex Medical, Salt Lake City, UT) LAA occluder was deployed in 6 dogs via transseptal puncture under fluoroscopy and transesophageal

echocardiography (TEE). After confirming the position by TEE and multi-angle fluoroscopy, the occluder was released to seal the LAA ostium. Local and systemic histopathology was assessed 30 days after device implantation.
Results: By pre-implant angiography and TEE, the mean diameter of LAA ostium was 15.9±2.5mm and15.8±2.5mm, respectively. LAA occlusion devices, clinically indicated for 14~20mm human LAA ostial diameter, were successfully implanted in 6 animals without pericardial effusion or other procedure- or device-related complications. Post-operative TEE showed all devices in the intended positions achieving successful closure of all LAA ostia (Figure a). Minimal peri-device leaks (< 3mm jet) were noted in 2/6 cases. Animals experienced no adverse events over 30 days post-implant. Histological analysis showed adequate deployment and complete circumferential occlusion of all 6 appendages after 30 days. Full endothelial coverage of the luminal aspect of the occluder was found with no surface thrombosis (Figure b). No adverse histology findings were noted in the myocardia, mitral valves, kidneys or brains.

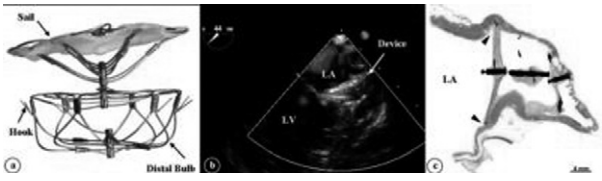
Conclusions: In a 30-day canine study the Coherex WaveCrest™ demonstrated safe deployment, durable LAA occlusion and favorable biocompatibility.

TCT-765

First In-Vivo Evaluation of the Ultrasept Left Atrial Appendage Closure Device

Yanping Cheng[1], Gerard Conditt[1], Genghua Yi[1], Alyssa Wagner[1], Patricia Mount[1], Armando Tellez[1], Serge Rousselle[2], Greg Kaluza[1], Juan Granada[1]
[1]Cardiovascular Research Foundation, Orangeburg, NY, [2]Alizée Pathology, LLC, Thurmont, MD

Background: Left atrial appendage (LAA) occlusion aims to reduce the risk of stroke in atrial fibrillation patients. In this study, we evaluated the feasibility and long-term safety of the Ultrasept LAA closure device (Figure a)(Cardia Inc., Eagan, MN) in a canine model.
Methods: Trans-septal puncture and device deployment was guided under fluoroscopy and transesophageal echo (TEE) in 5 dogs. First, the distal cylindrical bulb was released and secured to the appendage wall with hooks and then the proximal sail was unfolded and covered the LAA ostium. Rotational angiography, TEE and histology outcomes were assessed 30 days following implantation.
Results: Pre-operative TEE showed mean diameter of the LAA ostium= 17.2±1.6mm, depth= 18.5±1.7mm and landing zone for the distal bulb= 12.8±1.3mm. The mean bulb diameter implant was 16.8±1.8 mm. Post-operative TEE showed adequate position and successful occlusion in all implanted devices. Small pericardial effusion related to multiple device attempts was noted in 1 animal. At 30 days, TEE showed full occlusion of all LAA ostia (Figure b) besides a minimal peri-device leak (<3mm) in 1 animal. No pericardial effusion or device-related thrombus formation were found. Histological analysis confirmed circumferential occlusion of all appendages and complete neointimal coverage on the luminal aspect of the occluder (Figure c).



Conclusions: The percutaneous delivery of the Ultrasept LAA occlusion device was feasible and safe in a canine model. At 30 days, all devices displayed complete healing and occlusion of the LAA without any adverse events.

TCT-766

Early Safety of the Amplatzer Cardiac Plug™ for Left Atrial Appendage Occlusion

David Meerkin[1], Adi Butnaru[1], Dmitry Dratva[1], Olivier Bertrand[2], Dan Tzivoni[1]
[1]Shaare Zedek Medical Center, Jerusalem, Israel, [2]Université Laval, Quebec City, Canada

Background: Following strong evidence that the left atrial appendage (LAA) is the site of the majority of thrombus formation within the left atrium in patients with non-valvular atrial fibrillation, non-pharmacological approaches to LAA exclusion have been developed and shown to be effective. We aim to assess the cumulative experience of a single operator using a strict set of deployment and release criteria for the Amplatzer Cardiac Plug (ACP, St. Jude Medical, Plymouth, MN) and the impact of these criteria on procedural success and complications.
Methods: Procedural and in-hospital outcomes of LAA occlusion performed by a single operator using the ACP in 100 anticoagulant ineligible patients with a high stroke risk were assessed.
Results: One hundred patients with a mean CHADS2 score of 3.21±1.23 underwent catheterization for closure of LAA with the ACP. The mean landing zone as assessed by TEE was 20.01±3.21 mm, and 20.8±3.19 mm by fluoroscopy. The mean difference between the TEE and the fluoroscopic measurements was 0.8±1.13 mm. Device deployment was successful in 100/100 attempted cases with a mean deployed device size of 24.36±3.27 mm. In 82 of the 100 cases the first device selected was implanted. Procedural and in-hospital complications were limited to a single case of pericardial tamponade and one post-procedural pulmonary oedema both of which were adequately treated with no long-term sequelae.
Conclusions: In this single operator report, LAA occlusion using the double element ACP can be safely performed with excellent success rates. Using very specific deployment success, stability and release criteria, this device can achieve LAA occlusion with extremely low complication rates in an extremely frail oral anticoagulant ineligible population with multiple co-morbidities.

TCT-767

Long-term Outcomes Following Percutaneous Left Atrial Appendage Closure with the Amplatzer Cardiac Plug Device in Patients with Non-Valvular Atrial Fibrillation and Contraindications for Anticoagulation Therapy

Josep Rodes-Cabau[1], Arsene Basmadjian[2], Jean Champagne[3], Albert Chan[4], Melanie Freeman[5], Xavier Freixa[6], Eric Horlick[7], Reda Ibrahim[8], Webb John[9], Jean-Francois Marquis[10], Mark Osten[11], Jacqueline Saw[12], Marina Urena[13]
[1]Quebec Heart and Lung Institute, Quebec, Canada, [2]Montreal Heart Institute, Montreal, quebec, [3]Quebec Heart and Lung Institute, Quebec, Quebec, [4]Royal Columbian Hospital, New Westminster, BC, [5]St Pauls Hospital, Vancouver, British Columbia, [6]Montreal Heart Institute, Montreal, QC, [7]University of Toronto, Toronto, Canada, [8]Montreal Heart Institute, Montreal, Quebec, [9]St Pauls Hospital, vancouver, british Columbia, [10]University of Ottawa Heart Institute, Ottawa, Ontario, [11]Toronto General Hospital, University of Toronto, Toronto, Ontario, [12]Vancouver General Hospital, Vancouver, British Columbia, [13]Quebec Lung and Heart Institute, Laval University, Québec, Quebec

Background: Little data exist on the long-term outcomes following LAA closure in patients with absolute contraindication for warfarin.
Methods: A total of 52 patients (mean age: 74± 8 years, median CHADS2 score: 3 [2-4]) underwent LAA closure using the ACP device in 7 Canadian centers. Most patients received short-term (1-3 months) dual antiplatelet therapy following the procedure and single antiplatelet therapy thereafter, and no patient was lost to follow-up (≥12 months in all patients). Transesophageal echocardiography (TEE) was performed in 74% of patients at 6-month follow-up. Peridevice residual leak was defined as mild (flow width: 1-3 mm) or severe (flow width: ≥3 mm).
Results: The procedure was successful in 98.1% of the patients, and was associated with a low rate of periprocedural complications (device embolization: 1.9%, no stroke or pericardial effusion). At a mean follow-up of 20 ± 5 months, the rates of death, stroke, systemic embolism, severe pericardial effusion, and major bleeding were 5.8%, 1.9%, 0%, 1.9%, and 1.9%, respectively. TEE at follow-up showed the presence of mild peridevice leak in 16.2% of patients. There were no cases of device thrombosis.
Conclusions: In patients with NVAF at high risk for cardioembolism and absolute contraindication for anticoagulation, LAA closure using the ACP device followed by dual/single antiplatelet therapy was associated with a very low rate of cardioembolic and bleeding events at 2-year follow-up. No cases of severe residual leak or device thrombosis were observed at 6-month follow-up.

POSTERS